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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|------------------------|---|----------------------|-------------------------|-------------------|--|
| 09/662,927 | 09/15/2000 | Marvin J. Slepian | MJS 101 | 3540 | |
| 23579 | 7590 02/06/2004 | EXAMINER | | INER | |
| | PATREA L. PABST | | | KREMER, MATTHEW J | |
| | HOLLAND & KNIGHT LLP SUITE 2000, ONE ATLANTIC CENTER | | | PAPER NUMBER | |
| | 1201 WEST PEACHTREE STREET, N.E. | | | ١ د. | |
| ATLANTA, GA 30309-3400 | | | DATE MAILED: 02/06/2004 | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

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|---|---|--|--|---------------------|
| \ | | Application No. | Applicant(s) | |
| | | 09/662,927 | SLEPIAN, MA | ARVIN J. |
| Office Action Sui | nmary | Examiner | Art Unit | |
| | | Matthew J Kremer | 3736 | |
| The MAILING DATE of the Period for Reply | is communication ap | pears on the cover sh | eet with the correspondence | e address |
| A SHORTENED STATUTORY THE MAILING DATE OF THIS - Extensions of time may be available under after SIX (6) MONTHS from the mailing of the period for reply specified above is left if NO period for reply is specified above. - Failure to reply within the set or extended Any reply received by the Office later that earned patent term adjustment. See 37 (6) | COMMUNICATION. In the provisions of 37 CFR 1. ate of this communication. Iss than thirty (30) days, a replay the maximum statutory period period for reply will, by statut three months after the mailin | 136(a). In no event, however, bly within the statutory minimu will apply and will expire SIX te, cause the application to be | may a reply be timely filed m of thirty (30) days will be considered (6) MONTHS from the mailing date of come ABANDONED (35 U.S.C. § 133 | this communication. |
| Status | | | | |
| Responsive to communication is FINAL. 3) Since this application is it closed in accordance with | 2b)∐ Thi n condition for allowa | s action is non-final. | al matters, prosecution as to 35 C.D. 11, 453 O.G. 213. | o the merits is |
| Disposition of Claims | | | • | |
| 4) ⊠ Claim(s) 1-9,19,22,23,27 4a) Of the above claim(s) 5) □ Claim(s) is/are allowing | is/are withdra owed. are rejected. 27, 28, and 30-32 is | awn from considerations s/are objected to. | on. | |
| Application Papers | | | | |
| · · · · · · · · · · · · · · · · · · · | is/are: a) acc hat any objection to the t(s) including the correc | cepted or b) object e drawing(s) be held in a ction is required if the d | abeyance. See 37 CFR 1.85(rawing(s) is objected to. See 3 | 37 CFR 1.121(d). |
| Priority under 35 U.S.C. § 119 | | | | |
| 2. Certified copies of3. Copies of the certified | None of: the priority documen the priority documen fied copies of the prior e International Burea | nts have been receivents have been receivents have been receivents have been to the things of the th | ed. ed in Application No been received in this Nation). | |
| Attachment(s) 1) Notice of References Cited (PTO-89) 2) Notice of Draftsperson's Patent Draw 3) Information Disclosure Statement(s) Paper No(s)/Mail Date | ring Review (PTO-948) | Pap 5) Do | erview Summary (PTO-413) per No(s)/Mail Date tice of Informal Patent Application per: | (PTO-152) |

Application/Control Number: 09/662,927 Page 2

Art Unit: 3736

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-5, 9, and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 4,505,710 to Collins. Collins et al teaches a sensor (Freon 11) which directly interacts with the implanted device through the one actuator (diaphragm that causes expulsion of the drug). (column 4, lines 46-50 of Collins). In regard to claims 2 and 3, a memory chip is disclosed, which is considered a data storage means. (column ,4 lines 20-27 of Collins). In regard to claims 4-5, a telemetry means is disclosed. (column 5, lines 49-62 of Collins In regard to claim 9, the sensor detects a change in temperature in the device caused by the heater. (column 4, lines 46-50 of Collins). In regard to claim 33, an override capacity is disclosed, which means the sensor and actuator are configured for control by an external device. (column 6, lines 35-43 of Collins).

Response to Arguments

3. Applicant's arguments with respect to claims 1-5, 9, and 33 have been considered but are moot in view of the new ground(s) of rejection.

Application/Control Number: 09/662,927 Page 3

Art Unit: 3736

Allowable Subject Matter

4. Claims 6-8, 19, 22, 23, 27, 28, and 30-32 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

5. The following is a statement of reasons for the indication of allowable subject matter. The prior art does not teach or suggest "means for communication to one of a series of nested loops of information exchange," "an external input connected through loops to effectuate change in the device from the at least one actuator," "monitoring means configured for position external to the patient," "transmitting and receiving means to the one or more sensors," "means for remotely accessing the data," "means for transmitting or receiving data from a computer or phone communication means," "measuring fouling of the device or at least one sensor over time," "at least one sensor is configured to measure protein deposition or formation of a bacterial film on a biliary stent, increase in calcification of a urinary stent, and neointimal thickening of an arterial stent," and "one or more sensors configured for communicating information to the monitoring means and to each other, and configured for communicating commands to the actuator."

Application/Control Number: 09/662,927 Page 4

Art Unit: 3736

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent 4,705,503 to Dorman et al. discloses an implanted device with sensors that detect a metabolite and an actuator (valve) that responds to the sensor.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J Kremer whose telephone number is 703-605-

Application/Control Number: 09/662,927

Art Unit: 3736

927 Page 5

0421. The examiner can normally be reached on Mon. through Fri. between 8:30 a.m. -

5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Max Hindenburg can be reached on 703-308-3130. The fax phone number

for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the

Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR.

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you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

Matthew Kremer Assistant Examiner

Art Unit 3736

MAX F. HINDENBURG

TECHNOLOGY CENTER 3700